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MAY 26 2011

5 510(k) Summary

5.1 Applicant and Correspondent

Name:	Filligent (HK) Limited
Address:	7th Floor, 69 Jervois Street Sheung Wan Hong Kong
Contact Person:	Melissa Mowbray-d'Arbela Chief Executive Officer
Phone:	(852) 2542 2400
Date of Preparation:	March 11, 2011

5.2 Manufacturer

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

5.3 Name of Device

Trade/Proprietary/Model Name: BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A
Premium BF-200-3013A

Common Name:	Surgical Facemask
Classification Name:	Mask, Surgical
Classification Regulation:	878.4040
Panel:	General Hospital
Product Code:	OUK
Recognized Performance Std:	ASTM F2100-07 (refer to submission)

5.4 Devices to Which New Device is Substantially Equivalent

Device Name:	Prestige Ameritech Face Mask
Manufacturer:	Prestige Ameritech
Reference:	K061716

5.5 Device Description

The BioFriend™ BioMask™ surgical facemask is offered in two mask styles, Model: BF-200-2001A ("Universal") and Model: BF-200-3013A ("Premium"). The Universal model is a standard flat mask with pleats, while the Premium model is flat-folded and expands into a convex-shaped mask. The Premium model also has ear adjusters and an anti-fog nose flap. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in these devices are typical construction materials commonly used in surgical facemasks and are being used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second inner layer is treated with copper and zinc. Both layers inactivate influenza viruses using different mechanisms of action. Masks are held in place on the wearer with elastic loops and contain a malleable metal nosepiece strip.

5.6 Statement of Intended Use

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks inactivate 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

There are two models: (1) Universal (BF-200-2001A) - is a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

5.7 Summary of Technological Characteristics

The BioFriend™ BioMask™ surgical facemasks have substantially equivalent filter and barrier properties as the predicate device, and conform to the recognized FDA consensus standard ASTM F2100-07 Standard Specification for Performance of Materials used in Medical Face Masks. Both models of the BioFriend™ BioMask™ surgical facemask are constructed from the same materials and layers, and are identical in all respects other than shape. The outer layer of both models is coated with a hydrophilic plastic that allows aerosolized droplets contacting the surface of the mask to be rapidly absorbed into the inner layers. Both the outer and second inner layers are treated with different compounds that independently inactivate viruses through different mechanisms of action. Laboratory *(in vitro)* test results demonstrate that the BioFriend™ BioMask™ surgical facemasks inactivate 99.99% (≥4-logs) of 15 different strains of Influenza A and B viruses, including the circulating 2009 pandemic H1N1, recent vaccine isolates, major reassortments and avian, swine and equine isolates after 5 minutes contact with the mask surface.

The BioFriend™ BioMask™ surgical facemasks have been tested for, and appropriately passed standardized tests for, fluid penetration resistance, particulate filtration efficiency, bacterial filtration efficiency, flammability, and breathing resistance. The device as a whole has been shown to be biocompatible through standardized tests for irritation, sensitization and extractables.

The materials of construction used in the BioFriend™ BioMask™ surgical facemasks are equivalent to those of the predicate device. The devices as a whole are substantially equivalent to the predicate device.

5.8 Brief description of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

- Bacterial Filtration Efficiency – ASTM F2101
- Sub-micron Particulate Filtration Efficiency – ASTM F2299
- Fluid Penetration Resistance – ASTM F1862
- Breathing Resistance – MIL-M-3654C
- Flammability Testing – 16 CFR 1610
- Biocompatibility, Irritation – ISO 10993-10
- Biocompatibility, Sensitization – ISO 10993-10
- Biocompatibility, Chemical Characterization – ISO 10993-18

5.9 Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Not applicable.

5.10 Conclusions drawn from the nonclinical and clinical tests

Standardized testing has shown that the construction materials used in both models of the BioFriend™ BioMask™ surgical facemask are substantially equivalent to those of the predicate device. The devices as a whole have been demonstrated to be biocompatible through irritation and sensitization testing, with toxicological assessment of the devices' components which could potentially be released with inhalation or salivary contact, indicating the devices are safe for use in the intended application. Laboratory testing has demonstrated the devices' efficacy. Both models of the BioFriend™ BioMask™ surgical facemask have been shown to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Filligent (HK) Limited
C/O Mr. Ian Gordon
Emergo Group, Incorporated
611 West 5th Street Third Floor
Austin, Texas 78701

MAY 26 2011

Re: K101128
Trade/Device Name: BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: OUK
Dated: May 20, 2011
Received: May 23, 2011

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number:

K101128.

Device Name:

BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A

Indications for Use:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w, which form ionic bonds with negatively-charged side-groups on influenza viruses).

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Prescription Use _____ (21 CFR 801 Subpart D)	AND/OR	Over-The Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K101128

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded and expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of microorganisms, body fluids and particulate material.